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"Delivery system for biological material"

Claims:

1. A composition for delivery of biological material into a target cell comprising:

biological material,
a preparation of an aqueous polymer system on the basis of a mixture with at least two compounds being incompatible in aqueous solutions, said compounds being present in a concentration in water that leads to formation of a discontinous phase by one of said compounds, said dispersed phase including microparticles in said aqueous solution.

2. A composition according to claim 1 wherein, the mixture is a water in water mixture.

3. A composition according to claims 1 or 2, wherein first and second compounds are carbohydrate-based polymers or derivatives thereof.

4. A composition according to claims 1 or 2, wherein first compound is a carbohydrate-based polymer or derivative thereof and second compound is a polyaliphatic alcohol or derivative thereof.

5. A composition according to one of the claims 1 to 4, wherein the carbohydrate-based polymer is dextran, or dextrin, or a methylcellulose

based polymer, or a carboxymethyl cellulose-based polymer, or polydextrose, or chitin, or chitosan, and/or starch, or hetastarch, or Ficoll, or derivatives thereof, or naturally occurring polymers as zein, and pullulan, or derivatives thereof.

6. A composition according to claim 5, wherein one compound is substituted by a nucleic acid-binding agent.

7. A composition according to one of the claims 4 to 6, wherein the polyaliphatic alcohol is polyethylene oxide, or a derivative thereof, or polyethylene glycol (PEG), or PEG-acrylate, or polyvinyl acetate, or a derivative thereof.

8. A composition according to one of the above claims, said composition comprising a surfactant or a derivative thereof.

9. A composition according to claim 8, wherein said surfactant is polyoxyethylene sorbitan and fat acid ether (Tween-20,40,60,80).

10. A composition according to one of the above claims, said composition comprising polyoxyethylene-polyoxypropylene co-polymer.

11. A composition according to claim 10, wherein said polyoxyethylene-polyoxypropylene co-polymer is Pluronic L-64 or Pluronic F-68, or a derivative thereof.

12. A composition according to one of the above claims, said composition comprising polyvinylpyrrolidone (PVP).

13. A composition according to one of the above claims, wherein said biological material comprises polynucleotides, or proteins, or peptides, or derivatives thereof.

14. A composition according to one of the above claims, wherein said biological material comprises cytokines or monoclonal antibodies

15. A composition according to claim 14, wherein said cytokines comprise interferones and/or interleukines.

16. A composition according to claim 6, wherein said nucleic acid- binding agent is a peptide or a protein.

17. A composition according to claim 16, wherein said peptide are low molecular weight polylysines or polyethylenimines or derivatives thereof.

18. A composition according to claim 16, wherein said protein is a histone.

19. A composition according to claim 5, wherein said dextran has a molecular weight from 4 kDa to 5000 kDa.

20. A composition according to claim 13, wherein said polynucleotide is DNA.

21. A composition according to claim 13, wherein said polynucleotide is RNA.

22. A composition according to claim 21, wherein said RNA is antisense.

23. A composition according to claim 7, wherein said is polyethylene glycol has a molecular weight from 1 kDa to 20 kDa.

24. A method for preparation of microparticles with use of a composition according to one of the above claims, wherein the concentration of

water for formation of microparticles is achieved by evaporation of water from a one-phase system leading to a phase separation.

25. A method according to claim 24, wherein said evaporating process has a duration between 0,1 and 100 hours.

26. A method according to claim 24 or 25, wherein said evaporating process is carried out at a temperature between 0° C and 100° C.

27. A method according to one of the claims 24 to 26, wherein said evaporating process is carried out under a pressure of 0,1 to 760 mm Hg p.

28. A method according to one of the claims 24 to 27, wherein said evaporating process is stopped when the water concentration within the system is between 5 to 75 %.

29. A method of applying a composition according to one of the above claims 1 to 28 to a cell culture.

30. Microparticles being formed by conducting a method according to one of the claims 24 to 29.

31. Microparticles according to claim 30 being composed of at least 75 % polymer molecules and 25 % or less biological material.

32. A composition for delivery of biological material into a target cell comprising:

biological material,
a preparation of an aqueous polymer system on the basis of an emulsion with at least two compounds being incompatible in aqueous solutions,

said compounds being present in a concentration in water that leads to formation of a dispersed phase by one of said compounds,
said dispersed phase including microparticles in said aqueous solution.

33. A composition according to claim 32 wherein, the emulsion is a water in water emulsion.

34. A composition according to claims 32 or 33, wherein first and second compounds are a carbohydrate-based polymers or derivatives thereof.

35. A composition according to claims 32 or 33, wherein first compound is a carbohydrate-based polymer or derivative thereof and second compound is a polyaliphatic alcohol or derivative thereof.

36. A composition according to one of the claims 32 to 35, wherein the carbohydrate-based polymer is dextran, or dextrin, or a methylcellulose based polymer, or a carboxymethyl cellulose-based polymer, or polydextrose, or chitin or chitosan, and/or starch, or hetastarch, or derivatives thereof, or naturally occurring polymers as zein, and pullulan, or derivatives thereof.

37. A composition according to claim 36, wherein one compound is substituted by a DNA-binding agent.

38. A composition according to one of the claims 35 to 37, wherein the polyaliphatic alcohol is polyethylene oxide, or a derivative thereof, or polyethylene glycol (PEG), or PEG-acrylate, or polyvinyl acetate, or a derivative thereof.

39. A composition according to one of the above claims, said composition comprising a surfactant or a derivative thereof.

40. A composition according to claim 39, wherein said surfactant is polyoxyethylene sorbitan (Tween-20,40,60,80).

41. A composition according to one of the above claims, said composition comprising co-polymers or block co-polymers.

42. A composition according to claim 41 wherein said co-polymer is poloxamer or Pluronic L-64 or Pluronic F-68, or a derivative thereof.

43. A composition according to one of the above claims, said composition comprising polyvinylpyrrolidone (PVP)

44. A composition according to one of the above claims, wherein said biological material comprises Polynucleotides, or Vaccines (microbes, viruses), or Proteins, or Peptides, or derivatives thereof.

45. A composition according to one of the above claims, wherein said biological material comprises Cytokines or monoclonal antibodies

46. A composition according to claim 45, wherein said Cytokines comprise Interferones or Interleukines,

47. A composition according to claim 37, wherein said DNA binding agent is a peptide or a protein.

48. A composition according to claim 47, wherein said peptide is a low molecular weight polylysines.

49. A composition according to claim 47, wherein said protein is a histone.

50. A composition according to claim 36, wherein said dextran has a molecular weight from 4 kDa to 5000 kDa.

51. A composition according to claim 44, wherein said polynucleotide is DNA.

52. A composition according to claim 44, wherein said polynucleotide is RNA.

53. A composition according to claim 52, wherein said RNA.is antisense.

54. A composition according to claim 38, wherein said is polyethyleneglycol has a molecular weight from 3 kDa to 20 kDa.

55. A method for preparation of microparticles with use of a composition according to one of the above claims, wherein the concentration of water for formation of microparticles is achieved by evaporation of water from a one-phase system leading to a phase separation.

56. A method according to claim 55, wherein said evaporating process has a duration between 0,1 and 50 hours.

57. A method according to claim 55 or 56, wherein said evaporating process is carried out at a temperature between 0° C and 50° C.

58. A method according to one of the claims 55 to 57, wherein said evaporating process is carried out under a pressure of 0,1 to 760 mm Hg p.

59. A method according to one of the claims 55 to 58, wherein said evaporating process is stopped when the water concentration within the system is between 5 to 80 %.

60. A method according to one of the claims 55 to 59, wherein the calcium phosphate precipitation method is used.

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